UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
1 Congress Street, Suite 1100
BOSTON, MA 02114-2023

FILE COPY

CERTIFIED MAIL

March 21, 2005

Michael A. Teague, Ph.D.
Vice President / ESHA
Clariant Corporation
4000 Monroe Road
Charlotte, North Carolina 28205

Re: Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, February 2005

Dear Dr. Teague:

This is in response to your *February 2005 Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214.* EPA's contractor, Versar, has completed its review of this submittal. Versar's comments are attached.

EPA expects Clariant to make any necessary revisions to the comprehensive assessments as soon as possible. Accordingly, EPA requests that Clariant provide its estimated schedule for completion of the revised assessments within 7 days of receipt of this letter.

Should you have any questions, please call me at (617) 918-1527 or by e-mail at tisa.kimberly@epa.gov.

Sincerely,

Kimberly N. Tisa, PCB Coordinator
Office of Ecosystem Protection

cc: T. Olivier, EPA
M. Milette, EPA

attachment

Versar inc.

MEMORANDUM

TO: Laura Casey

cc: 11.1126.1000.001.01

FROM: Diane Sinkowski, Jim Buchert

DATE: March 18, 2005

SUBJECT: Review of "Exposure and Screening-level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" (February 2005)

I have the reviewed the revised risk assessment and response to comments provided by Clariant, per the technical direction provided by EPA Region 1 on February 24, 2005, and have the following comments:

1. The volatilization factor, VF, calculated in this assessment is presented with the units of kg/m^3. A unit analysis of 3 of the equations seems to contradict this.

   - In Equations 1 and 9, the VF needs to be in units of m^3/kg, so that the inhalation factor can be added to the other factors in the denominator, which are in kg^2/mg. This yields the correct units for the PCB concentration in carpeting, CNC_{carpet} of mg/kg.
   - In Equation 8, if the units of Cg are mg/m^3, and the units of M are mg/kg, then the units of VF need to be m^3/kg.

2. Where does room surface area fit into these calculations? Is a certain area incorporated in the empirical equation used (Equation 2)? Typically, when an air concentration is calculated from soil or groundwater, the area of the source needs to be know and is incorporated into the calculation because a larger area results in a higher concentration.

Please feel free to contact me if you have any questions.

Versar inc.

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   Please feel free to contact me if you have any questions.

MEMORANDUM

To: Mr. Jim Buchert, Versar, Inc.

From: Laura Casey, OPPT/NPCD/FOB

RE: Technical Direction to Work Assignment 0-1

Subject: Clariant Corporation, Coventry, Rhode Island

EPA-Region 1 has received from the Clariant Corporation its response to Versar's January 23, 2005 comments on the *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios* dated December 6, 2004 (*Exposure Assessment)* associated with Clariant's Red Pigments. Clariant has also provided a revised *Exposure Assessment* incorporating Versar's comments, as applicable. EPA will provide both the response and the revised *Exposure Assessment* to Versar under separate cover.

Please review these documents for the following:

- Please review the response and the revised *Exposure Assessment* and determine if Clariant has adequately addressed Versar's comments.

Due Date: Please complete the review of these documents around by **March 17, 2005**. If there are any questions regarding this due date, please contact me at 202-566-1982.

Technical questions relating to this project may be addressed directly to Kim Tisa in Region 1 at 617-918-1527 or by e-mail at tisa.kimberly@epa.gov.

BBL®
BLASLAND, BOUCK & LEE, INC.
engineers, scientists, economists

February 21, 2005

Michael Teague, Ph.D.
Clariant Corporation
4000 Monroe Road
Charlotte, North Carolina 28205

Dear Dr. Teague:

We have reviewed the comment by USEPA and their contractor on the *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214* dated December 6, 2004. Generally, we agree with the comments submitted to us and remain appreciative of the thorough review of the submitted report. Where noted, the text was revised in the draft report, and in some instances changes were made to reflect concerns raised by the reviewers. I provide a specific response to each comment and identify how, where necessary, the document was modified.

Comment 1. The pathways considered seem appropriate for the exposure scenarios evaluated.

Response: None required.

Comment 2. Versar's previous comments have been adequately addressed.

Response: None required.

Comment 3a. On page 2-5, the risk assessment indicates that a soil dust ingestion rate of 55 mg per day was assumed for children and is based on data from Moya et al. (2004). I was unable to find this value in the cited reference. The Moya et al. reference states the following:

> *Children's mean soil ingestion values ranged from 39 mg/day to 271 mg/day with an average of 138 mg/day for soil ingestion and 193 mg/day for soil and dust ingestion. Upper percentile values average 358 mg/day for soil and 790 mg/day for soil and dust combined.*

Could Clariant please provide clarification on the origin of the assumed value?

Response: As described in the revised text, use of the upper bound estimates for multiple exposure variables results in an unintentional overestimation of exposure and unrealistically conservative bounding estimates. Since many of the exposure variables in the carpet exposure

scenario are based not on empirical data but on best scientific judgment, many were intentionally selected at the high-end of possible values to address uncertainty associated with the decision. Therefore, we considered the use of a mean or average concentration for dust ingestion in this setting to be appropriate, adequately protective, and consistent with USEPA Guidance (e.g., 1992 *Guidelines for Exposure Assessment*). Thus, the relevant text will be modified to read:

> *According to Moya et al. (2004), children consume an average of 193 mg of soil and dust per day. However, the authors also stated that the daily consumption of soil alone is 138 mg/day. Therefore, dust ingestion rate of 55 mg/day can be estimated by subtracting 138 mg/day from 193 mg/day. That value was used to approximate the daily fiber ingestion rate (Table 1).*

Comment 3b. Clariant should provide information regarding exposure frequency and duration for the food wrap scenario and revise the calculations shown at the bottom of page 3-2 accordingly, since the calculations only reflect one day's consumption of cheese. In particular, for carcinogenic risk, the calculated daily dose shown, 0.0000014 mg tPCBs/kg BW/day, cannot be compared to the target lifetime average daily dose of 0.000014 mg/kg BW/day (Table 1) without dividing by the lifetime averaging time (i.e., 25,550 days).

Response: The text relating to the calculation of the cancer risk will be edited as follows:

> *To estimate cancer risk, the estimated daily exposure must be averaged over a lifetime. According to Pao et al. (1990), the maximum consumption rate of natural cheese for all age groups and genders is 16.2%. Assuming that there are three meals per day, the number of eating occasions in one year equals to 1,095. Thus, the number of eating occasions where cheese is consumed equals to 177.39. Assuming three meals per day, this rate is equivalent to approximately 59 days out of 365 where cheese is consumed. This number was used as the exposure frequency. Exposure duration was set to 70 years and averaging time to 25,550 days. Multiplying the daily exposure rate of 0.0000014 mg tPCB/kg BW/day by 59 days/year and 70 years and dividing the product by 25,550 days yields a lifetime-averaged exposure rate of 0.0000002 mg tPCB BW/day. In terms of the cancer threshold (0.00001429 mg tPCB/kg BW/day; Table 1), the estimated exposure resulting from cheese consumption is about 63 times lower than that needed to exceed the cancer level risk of 1 in 1,000,000.*

Comment 3c. Table 1 (page 7-1) of the risk assessment indicates that a slope factor of 0.07 $(mg/kg/day)^{-1}$ was assumed for calculating the cancer risk from ingestion, dermal absorption, and inhalation of PCBs. The value is the upper-bound slope factor for PCBs of the lowest risk and persistence. EPA's criteria for use of this slope factor (www.epa.gov/iris/subst/0294.htm) is that congener or isomer analyses verify that congeners with more than 4 chlorines comprise less than 1/2% (0.5%) of total PCBs. Page 1-2 (bottom paragraph) of the risk assessment indicates that PCB congeners 44 and 70 make up approximately 90 percent of the total PCBs found in Pigment Red 144 and 214. It is uncertain from this statement whether the additional PCB congeners in the pigments are of low chlorine content.

Clariant should demonstrate to EPA that the composition of the pigments meets EPA's criteria for use of the 0.07 $(mg/kg/day)^{-1}$ slope factor.

Response: Results from Alta Labs congener analysis data previously presented to USEPA will be provided to illustrate that mono- through tetrachlorinated PCB congeners account for 0.1% to 0.4% of the total PCB concentration. These data support the use of the lowest cancer slope factor since they satisfy the criterion that less than 0.5% of the PCB mixture can be congeners with more than 4 chlorine substitutions.

Comment 4a. According to the risk assessment, Equation 4 (page 2-3) is obtained by substituting Equation 3 into Equation 2 (both on page 2-2), and solving for C_g... However, ..., the substitution has not been performed correctly... This correction should be made and any calculations performed using this equation should be revised.

Response: Indeed, the original manipulation of equations from Bennet and Furtaw (2004) lead to a substitution error. In reviewing the presented algorithm, further clarification of the arithmetical steps taken to estimate the parameters VF and M specific to the carpet scenario is provided in Section 2.1 of the revised document.

Comment 4b. The parameter M, as defined in the risk assessment, is incorrect. Table 1 (page 7-1) of the risk assessment indicates that M is the carpet area mass (face weight; mg/m^2). The parameter M, as defined in the Bennett and Furtaw (2004) and the Won, et al. (2000) papers is the mass of the compound [PCBs] collected on the sink [carpeting] pet unit area (mg/m^2). Therefore, the value shown in Table 1 for the carpet area mass and the calculated air concentration in an enclosed space 7 days post installation of a new carpet are incorrect, unless Clariant means to assume that the entire mass of the carpet is tPCBs.

Response: We agree that the current definition of parameter M is not consistent with that presented by Bennet and Furtaw (2004) and Won et al. (2000). The risk assessment report will be revised to include the correct definition.

Comment 4c. Equation 5 from the risk assessment has parameters representing the tPCB concentration in the carpeting (CC_{carpet}) and the concentration in the air (C_g). There cannot be two concentration parameters in the equation. When a unit analysis is done, one can see that the ingestion and dermal absorption parameters cancel to mg/kg as they should, since the equation is being solved for CC_{carpet} which is in units of mg/kg. However, when the units for the inhalation contribution to the equation are cancelled, the term is unitless instead of being mg/kg. Equation 5 and the calculations for CC_{carpet} should be revised.

Response: The revised calculations (referred to in Comment 4a and found in Section 2.1) yield correct units.

Comment 4d. A volatilization rate factor, VRF, is included in the inhalation exposure calculation. However, since the equation from the Bennett and Furtaw (2004)

paper, already takes into account desorption of the compound (tPCBs) from the sink material (carpeting), a VRF should not be included in the calculation if the methodology from the Bennet and Furtaw paper is to be used to calculate a tPCB air concentration.

Response: A volatilization *retention* factor, VRF, should remain because it serves a different purpose. The study by Bennet and Furtaw (2004) examines dynamics of volatile substances, present as a *layer*, from carpet in a closed system. Indeed, it implicitly accounts for the sorption/desorption dynamics. However, it only deals with surfaces and not carpet fiber matrix where the pigment is encapsulated. Therefore, VRF is used to model the proportion of tPCBs that may be liberated from the interior of the fiber as opposed to fiber surfaces alone. Ignoring this phenomenon would make the assessment unduly conservative and unrealistic.

Comment 4e. A bioavailability factor, (assumed values were 1, 5, 10, 50, and 100%, see Table 1), was included in the calculation of the ingestion dose. Although EPA has studied and provided some guidance regarding the relative bioavailability of metals, such as lead, at this time, U.S. EPA has not provided guidance for PCBs. Until EPA reviews all the studies on PCBs and comes to a consensus regarding the relative bioavailability of PCBs in soil, no bioavailability factors should be included when calculating PCB intakes via the ingestion pathway.

Response: The primary purpose of including the bioavailability factor is to acknowledge, in a quantitative sense, the unique conditions of the carpet production and coloring process. During this process, the pigment (and associated PCBs) is permanently encapsulated in the polymer shell of the fiber during the coloring process, and PCBs are unlikely to be as easily mobilized off the fiber as they would in the soil matrix. Thus, even if USEPA has not promulgated a bioavailability factor for soil, as the comment suggests, this should not prevent the consideration of this factor in estimating exposure and dose. Carpet fiber and soil represent very different environmental conditions. [In fact, in 1986, EPA published the *Development of Advisory Levels for Polychlorinated Biphenyls (PCBs) Cleanup* in which the Agency used an "Absorption Factor" of 0.3 for soil ingestion.] Moreover, as described in the report, even if there are no bioavailability data for carpet fiber, empirical and observational evidence dictates that it cannot possibly be 100%. Therefore, the factor should remain because it provides a proper perspective when making a risk management decision.

Once again, we would like to thank USEPA for their careful and a very constructive review and we welcome further dialogue to resolve any outstanding issues. If you have any questions, please do not hesitate to contact me at your convenience.

Sincerely,

John D. Schell, Ph.D.
Principal/Toxicologist

2929 Briarpark Drive • Suite 329 • Houston, TX 77042-3745
Tel (713) 785-1680 • Fax (713) 785-1640 • www.bbl-inc.com • Offices Nationwide

EXPOSURE AND SCREENING-LEVEL RISK ASSESSMENT FOR CARPET FIBER AND FOOD WRAP SCENARIOS ASSOCIATED WITH PIGMENT RED 144/214

Prepared for Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205

Prepared by BBL Sciences
2940 Kerry Forest Parkway
Tallahassee, Florida 32309

February, 2005

Table of Contents

1. Introduction

Clariant Corporation (Clariant) manufactures a wide range of specialty chemicals, including pigments for various industrial and household products. Two of these pigments, Pigment Red 144 and 214, have been produced at the Coventry, Rhode Island facility since about 2002. The synthesis of these di- and trichloroaniline-based pigments has the potential to inadvertently generate several congeners of polychlorinated biphenyls (referred to as total PCBs, or "tPCBs"). This has been recognized by the U. S. Environmental Protection Agency (USEPA) and accounted for in its rulemakings (see 48 Federal Register 50846, November 1, 1983). Recently, Clariant Corporation (Coventry facility) discovered that approximately 19 commercial lots of pigment formula contained tPCBs in excess of the 50-part-per-million (ppm) maximum permitted concentration. Although Clariant halted the production of these pigments after this discovery on September 9, 2003, certain amounts of the product were released into the stream of commerce. Clariant notified its direct customers regarding the problem and requested the return of any unused pigment material. Clariant also accepted returns of processed materials containing the pigment. Furthermore, Clariant performed several risk assessments of the pigments' impact on its manufacturing processes, as well as on some end use applications.

To assess the likelihood for exposure and risk to human receptors associated with the potential release from the non-compliant pigment, Clariant constructed a Conceptual Exposure Model (CEM) (Blasland, Bouck & Lee, Inc. [BBL], 2004). A CEM forms the basis for identifying exposure scenarios that require evaluation in a risk assessment context. Developed from existing information and relevant data, a CEM characterizes all potential or suspected sources of a chemical or chemicals of concern, types and concentrations of chemicals detected in primary products, transportation and distribution of primary products to secondary users, potentially affected media, and potential exposure pathways, including potential receptors. The objective of a pigment-specific CEM is to evaluate existing product-specific data to develop an understanding of the potential nature, extent, and distribution of tPCB-containing products and to identify significant data gaps. The exposure scenarios that are identified during the development of a CEM are a function of the potentially exposed population, the quantities of the product sold, the possible routes of exposure to chemicals of concern, and the pathways by which chemicals of concern reach a human receptor.

The CEM (BBL, 2004) identified fiber/carpet yarn and food wrap as two scenarios that required further attention in a more detailed analysis. The current screening-level risk assessment fulfills that requirement by conducting separate exposure and risk assessments for children potentially exposed to carpet fiber and for the general population potentially exposed to food wrap. The goal of this screening-level risk assessment is to

calculate risk-based levels of tPCBs in carpet yarn and fiber using cancer and non-cancer risk/hazard thresholds and children-specific exposure factors. For the food wrap scenario, a separate risk assessment is performed using information published in the Federal Register (62 Fed. Reg. 9365, March 3, 1997) and the maximum concentration of tPCBs contained in the tinted food wrap.

One concern expressed by the USEPA in its review of the CEM was the potential for the release of pigment from a production facility, and subsequent exposure via fugitive dust. However, this is not considered a potential complete exposure pathway for the following reasons. First, the pigments containing Pigment Red 144 and 214 are no longer produced with concentrations of tPCBs that exceed the regulatory limit, and the large proportion of pigments not incorporated into end products have been returned to the producer. Since Clariant is not aware of any spills reported at any production facility, and the contaminated pigments are no longer produced, the potential for a "release from production activities" is extremely minute. Second, the pigments were not produced in the quantity that would result in large amounts of material being stored or unused, thus reducing the potential for a major spill. Also, because it was a valued product, the handling of the material was such so as to limit the loss of material during the production activities. Finally, Pigment Red 144 and 214 are brightly colored powder pigments; if there had been a spill, it would not have gone unnoticed, and it would have been cleaned up right away. Therefore, a spill would not represent a long-term exposure to workers.

Because of the unique nature of the exposure scenario, many of the parameters needed to quantify risks, or calculate risk-based concentrations, are not readily available. Due to this lack of information, it was necessary to estimate certain key variables using best professional judgment. This resulted in the introduction of some uncertainty. Therefore, the estimated variables were typically intentionally overestimated, and they represented high-end exposure conditions. Addressing uncertainty in this fashion is consistent with USEPA recommendations and guidance (USEPA, 2001). Because of the conservative approach, this assessment is reflective of the screening-level step in the human health risk assessment process. That is, many of the exposure variables were set at the high end of the expected values, with the result of this redundant conservatism being risk-based concentrations that do not represent toxicological thresholds, but rather levels that are clearly without risks. Identification of pathways and chemical concentrations that are without significant risks is the purpose of the screening-level risk assessment.

The current screening-level risk assessment focuses on tPCBs from Pigment Red 144 and 214. From a risk perspective, total PCBs are considered as the chemicals of potential concern. In particular, because PCB congeners 44 and 70 make up about 90% of the tPCBs found in the pigments, these two congeners are used to characterize the physico-chemical properties of the tPCBs contained in the pigment.

2. Carpet Scenario

The primary receptors for this analysis are young children (1 to 10 years old), who may be exposed to tPCBs in the pigments via daily activities on carpeted surfaces. This potentially highly exposed population subgroup was chosen to reflect the conservative nature of the screening-level risk assessment. The activities assumed to lead to potential exposure consist of:

1. Mouthing of carpet surfaces, toys, hands, and feet, leading to the ingestion of the associated carpet fiber and dust;
2. Crawling, walking, and kneeling, leading to dermal uptake via the exposed skin; and
3. General day-to-day indoor activities, leading to the inhalation of fibers, dust, and tPCB vapors suspended in the air.

The extent of contact between children and carpet-borne constituents of concern is calculated via a deterministic exposure model. This model considers ingestion, dermal uptake, and inhalation exposure routes. The model and the associated input parameters are discussed below.

2.1 Exposure Model

To calculate the acceptable concentration of tPCBs in carpet by adopting child-specific exposure parameters and USEPA-promulgated, PCB-specific, non-cancer reference doses and cancer risk slope factors, an algorithm based on USEPAs (2002) guidance was modified to assess the carpet fiber exposure scenario.

2.1.1 Non-Cancer Hazard

The combined exposures calculation model for non-cancer hazard is as follows:

$$CNC_{Carpet} = \frac{THQ \cdot BW \cdot AT_{nc}}{ED \cdot EF\left[\left(\frac{1}{RfD} \cdot \frac{IR \cdot BioAF}{10^6 mg/kg}\right) + \left(\frac{1}{RfD} \cdot \frac{SA \cdot AF \cdot DERM}{10^6 mg/kg}\right) + \left(\frac{1}{RfD} \cdot IHR \cdot \frac{1}{VF} \cdot VRF\right)\right]} \qquad \textbf{Equation 1}$$

where,

CNC_{Carpet}-risk-based concentration in carpet fiber associated with hazard quotient of 1 (mg/kg),
THQ-target hazard quotient (unitless),
BW-body weight (kg)
RfD-non-cancer reference dose (mg/kg BW/day),
AT_{nc}-non-cancer averaging time (days),
ED-exposure duration (yrs),
EF-exposure frequency (days/yr),
IR-dust ingestion rate (mg/day),
BioAF-bioavailability factor for ingestion (unitless),
SA-contact skin surface area (cm^2/day),
AF-dust adherence factor (mg/cm^2),
DERM-dermal absorption factor (unitless),
IHR-inhalation rate (m^3/day),
VF-volatilization factor (kg/m^3), and
VRF-volatilization retention factor (unitless).

The volatization factor (*VF*) used in the above equation was calculated via a set of concentration relationships derived experimentally for an enclosed chamber containing a carpet sample impregnated with a substance of interest (Bennet and Furtaw, 2004 citing Won et al., 2000). The relationships describing carpet surface to air partitioning (K_{SA}) are as follows:

$$K_{SA} = \frac{\frac{k_s}{k_d}}{d_w} = 10^{3.82 - 0.62 \log VP} \qquad \textbf{Equation 2}$$

where,

$$\frac{k_s}{k_d} = \frac{M}{C_g} \qquad \textbf{Equation 3}$$

substituting Equation 3 into Equation 2 and solving for M yields,

$$M = (d_w \cdot 10^{3.83-0.62\log VP} \cdot C_g) \qquad \textbf{Equation 4}$$

where,

k_s-adsorption coefficient (m/hr),
k_d-desorption coefficient (m/hr),
d_w-carpet thickness (m),
VP-vapor pressure (Pa),
C_g-acceptable concentration of PCBs air from Equation 1 and 9 (mg/m^3), and
M-mass of PCBs per area of carpet (mg/m^2).

To express M on carpet weight basis, this parameter can be divided by carpet face weight (FW; kg/m^2) such that

$$M = \frac{(d_w \cdot 10^{3.83-0.62\log VP} \cdot C_g)}{FW} \qquad \textbf{Equation 5}$$

Furthermore, in realistic conditions of a normal house, ventilation is provided to maintain proper air quality. Therefore, the M term must allow for a dilution factor (AE; unitless) to avert modeling unrealistically high concentrations. Thus, Equation 5 is modified to

$$M = \frac{d_w \cdot 10^{3.83-0.62\log VP} \cdot C_g \cdot AE}{FW} \qquad \textbf{Equation 6}$$

The volatilization factor (VF; kg/m^3) is derived by dividing M by the air concentration term Cg (Equation 7). The VF is inserted into Equation 1 to calculate an acceptable carpet concentration attributable to tPCB volatilization.

$$VF = \frac{M}{C_g} = \frac{(d_w \cdot 10^{3.83-0.62\log VP} \cdot AE)}{FW}$$ **Equation 7**

Given that C_g is calculated in Equation 1 and 9 using the inhalation exposure assumptions, *VF* is inserted in these equations to derive an acceptable concentration in carpet fiber (*M;* mg/kg).

$$VF^{*}Cg = M$$ **Equation 8**

Calculations were repeated for bioavailability factors of 0.01, 0.05, 0.1, 0.5, and 1 and for volatilization retention factors (*VRF*) of 0.001, 0.005, and 0.01. The *VRF* is used to model the proportion of tPCBs that may be liberated from the interior of the fiber as opposed to fiber surfaces alone. The bioavailability factor accounts for consideration of differences in absorption efficiencies of carpet-bound tPCBs via the gut. The reason for handling these parameters as variables is described in the Uncertainty Section of this report (Section 4). The input variable parameterization is summarized in Section 2.2, as well as in Table 1.

2.1.2 Cancer Risk

The combined exposures back-calculation model for cancer risk is as follows:

$$CC_{Carpet} = \frac{TR \cdot BW \cdot AT_c}{ED \cdot EF\left[\left(\frac{CSF \cdot IR \cdot BioAF}{10^6 mg/kg}\right) + \left(\frac{CSF \cdot SA \cdot AF \cdot DERM}{10^6 mg/kg}\right) + \left(CSF \cdot IHR \cdot \frac{1}{VF} \cdot VRF\right)\right]}$$ **Equation 9**

where,

CC_{Carpet}-risk-based concentration in carpet associated with 1 x 10^{-6} cancer risk (mg/kg),

TR-target cancer risk,

BW-body weight (kg)

CSF-cancer slope factor (mg/kg BW/day)$^{-1}$,

AT_c-cancer averaging time (days),

ED-exposure duration (yrs),

EF-exposure frequency (days/yr),

IR-dust ingestion rate (mg/day),

BioAF-bioavailability factor for ingestion (unitless),

SA-contact skin surface area (cm^2/day),

AF-dust adherence factor (mg/cm^2),

IHR-inhalation rate (m^3/day),

DERM-dermal uptake factor (unitless),

VF-volatilization factor (kg/m^3), and

VRF-volatilization retention factor (unitless).

Calculations for cancer risk were also repeated for bioavailability factors of 0.01, 0.05, 0.1, 0.5, and 1, as well as for volatilization retention factors of 0.001, 0.005, and 0.01.

2.2 Model Parameterization

The exposure parameters, models, concentration data, risk factors, and assumptions used in the current assessment were obtained from a number of sources, including the USEPA guidance documents, published literature, the internet, and Clariant's database. Input parameters are summarized in Table 1. The paragraphs below discuss each input parameter in detail.

2.2.1 Body Weight

The receptor of interest in the carpet scenario is a young child who is expected to be in direct contact with carpeted surfaces as a result of normal daily activities such as playing, walking, and crawling. The range of age within this group can conceivably span from 1 to 10 years. The calculated average body weight for children of that age is 21.8 kg (USEPA, 2000) (Table 1).

2.2.2 Temporal Parameters

The time scale of the exposure and risk estimate is set to coincide with the useful life span of a residential carpet. According to an industry source, carpet warranties may span from 5 to 20 years. However, a typical carpet lasts about 10 years (Bigger and Bigger, 2004). Therefore, the exposure duration in this assessment was assumed to be 10 years. This is equivalent to the 3650 days used as the averaging time in non-cancer hazard calculations. For the cancer risk assessment, a default life expectancy of 70 years was used to derive the lifetime average daily dose (25,550 days) (USEPA 1997, 2002) (Table 1). The exposure frequency was set to the default of 350 days per year (USEPA 1997, 2002) and the event frequency at one event per day.

2.2.3 Ingestion Parameters

The primary mode of tPCB intake in this exposure scenario is assumed to be via the incidental ingestion of carpet fibers/dust as a result of mouthing of carpet surfaces, toys, hands, and feet. Because no ingestion rate data for the carpet fiber were readily available in the published literature, a conservative assumption was made that the carpet fiber intake by children is comparable to that of soil dust. According to Moya et al. (2004), children consume an average of 193 mg of soil and dust per day. However, the authors also stated that the daily consumption of soil alone is 138 mg/day. Therefore, an average dust ingestion rate of 55 mg/day can be estimated by subtracting 138 mg/day from 193 mg/day. That value was used to approximate the daily fiber ingestion rate (Table 1). Using an average for some exposure variables, and not setting them all at their high-end values in order to prevent the calculation of "unrealistically conservative bounding estimates," is consistent with USEPA risk assessment guidance (USEPA, 1992) This is a conservative assumption because, unlike loose soil particles, carpet fibers are not easily displaced because they are designed specifically to hold fast to the carpet backing.

A bioavailability factor was introduced into this component of the exposure/risk model to account for the proportion of the tPCBs in carpet that may be dislodged via the digestive tract activities. This factor was set to range from 1 to 100% (Table 1) due to the uncertainty as to its real empirical magnitude. At this time, the bioavailability factor remains a data gap and it is viewed as a crucial component of the overall risk assessment.

Recent studies suggest that the bioavailability of lipophilic compounds like tPCBs and dioxins are reduced when adsorbed to the soil matrix. Ruby et al. (2002) reported that the bioaccessibility (a surrogate for oral bioavailability) of low concentrations of polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) ranged from 19 to 34%. Similar results were reported by Hack and Selenka (1996) for

PCBs in a "standardized gastro-intestinal model." Although carpet fibers may differ from soil in important physical parameters affecting intestinal absorption, it is important to note the tPCBs in the pigment are permanently encapsulated in the polymer shell of the fiber during the coloring process and are unlikely to be as easily mobilized off the fiber as they are in the soil matrix. Therefore, even the assumption of 1% "bioavailability" likely overestimates the fraction of tPCBs available for absorption.

2.2.4 Inhalation Parameters

The inhalation rate of the receptor was set at 10.4 m^3/day, which is the average estimate for children ranging in age from 1 to 10 years old (USEPA, 2000) (Table 1). Although PCBs are large molecules and have only limited volatility at room temperature, an assumption was made that some amount may enter the room air and be available to be inhaled. The tPCB vapor contribution to the overall exposure burden was estimated via a set of empirical models derived from air chamber experiments (Equations 2 to 4; Bennet and Furtaw, 2004). The required parameters in these models include carpet thickness, carpet area mass (also called face weight), and vapor pressure. Average carpet thickness was set to 0.0129 m, and face weight to 1,700,000 mg/m^2 based on information obtained from the carpet industry (Radiant Panel Association [RPA], 2004; Carpet USA, 2004) (Table 1). The vapor pressure parameter was set to 0.0069 Pa and consisted of a mean of all values for PCB congeners 44 and 70 reported in the compendium by MacKay et al. (1992) (Table 1). To account for dilution due to ventilation, the air concentration estimated by Equation 4 was divided by the average number of air exchanges in a residential dwelling over 1 week. According to Murray and Burnmaster (1995), a house receives, on average, 18 air exchanges per day. This is equivalent to 126 exchanges per week. The application of this factor to the calculated air concentration yields a maximum room air concentration of 0.000009 mg tPCB/m^3 (Table 1). This estimate is very conservative because the current calculations implicitly assume that the tPCB load will be renewed (i.e, an inexhaustible source) in the carpet every 7 days over the carpet's life span of 10 years. Clearly, the estimated air concentration is much higher than what would be measured in an actual house with far more frequent ventilation rates and no possibility of tPCB replenishment.

The inhalation of tPCB-laden house dust containing carpet fibers was not explicitly accounted for in the exposure/risk models because initial calculations revealed that the relative contribution of tPCBs entering the receptor via this exposure route is exceedingly small even under the most conservative exposure assumptions. For example, assuming that 100% of the house dust consists of carpet fibers and that all of the tPCB fiber residue is available for uptake, the maximum concentration of tPCBs available for uptake is 3.8 mg/kg dust (maximum concentration of tPCBs measured in carpet fiber) (BBL, 2004). Long et al. (2000) reported that an average concentration of dust in a non-smoker's house is 3.6 µg/m^3. Multiplying that number by the daily

inhalation rate of a child (10.4 m^3/day; Table 1) yields a daily dust inhalation rate of 37.4 µg dust/day or 3.7 x 10^{-8} kg dust/day. Since the dust is assumed to contain 3.8 mg tPCBs/kg, the daily tPCB intake is 1.4 x 10^{-7} mg/day. Normalizing to the body weight of 21.8 kg (Table 1) yields an intake rate of 6.4 x 10^{-9} mg tPCB/kg BW/day. This value is nearly four orders of magnitude below the non-cancer and cancer hazard thresholds. Clearly, the relative contribution of house dust to the inhalation exposure route (and hazard/risk) is exceedingly small and, consequently, does not warrant explicit consideration in the exposure/risk model.

2.2.5 Dermal Uptake Parameters

Young children may spend much of their time crawling, walking, and kneeling. In an indoor environment, this may translate into dermal uptake via the exposed skin on knees, elbows, hands, and feet. According to the USEPA (2000), the skin surface area available for contact during warm-weather play, with 32% of the total skin surface area exposed, is 2,763 cm^2/day (Table 1). The adherence factor, or the amount of material remaining on the skin after contact, is estimated at 0.00724 mg/cm^2 (USEPA, 2000). This value reflects soil adherence for children, post-activity, indoors, on hands, arms, legs, and feet. Again, an assumption is made that carpet fibers behave similarly to soil particles. This represents an uncertainty in the assessment.

The USEPA's default value for the dermal absorption factor for tPCBs in soil of 14 % (USEPA, 2001) was adopted as the default value in this screening-level risk assessment. A recent report by Mayes et al. (2002) demonstrated that the dermal absorption of tPCBs from soil may be lower, approximating only 4% of the applied dose. Although carpet fibers may differ from soil in important physical parameters affecting dermal absorption, manufacturing processes also impact the amount of tPCBs available for absorption. The tPCBs in the pigment are permanently encapsulated in the polymer shell of the fiber during the coloring process and are unlikely to be as easily mobilized off the fiber as they are in the soil matrix. Thus, use of the default dermal absorption factor is likely an overestimate. Although there are no empirical data to quantify the amount of tPCBs that might be liberated from the carpet fiber, anecdotal evidence indicates that this is unlikely to be a significant amount. Individuals in contact with carpet, even young children crawling on the material, never show evidence of color transfer. For example, in the case of these pigments, children do not exhibit red knees, which would be evidence of a direct and substantial transfer of the encapsulated pigments (and tPCBs) onto the skin. As such, assuming a dermal absorption of 14% of the applied tPCBs from carpet substantially overestimates the exposure from this pathway.

2.3 Hazard and Risk Reference Values

Because no toxicity reference information for PCB 44 or 70 was available, the Aroclor 1254 reference dose was used as a surrogate. This is a very conservative step because an Aroclor mixture usually contains congeners that are assumed to be more persistent and potent than PCB 44 or 70. This further increases the degree of conservatism in the current assessment. The non-cancer reference dose for Aroclor 1254 is 0.00002 mg/kg/day (USEPA, 2002). The cancer slope factor of 0.07 $(mg/kg/day)^{-1}$ represents the lowest risk and persistence category recommended by the USEPA (2002). This value was selected because congener-specific data collected by Alta Labs demonstrated that the tPCB mixture present in the pigment contains from 0.1% to 0.4% of congeners with greater than four chlorines (Table 2). The target risk used in the calculation was the low end of the USEPA's "acceptable risk range" of one excess cancer in one million similarly exposed individuals (1×10^{-6}) (USEPA, 1996; 1997; 2000) (Table 1). The target hazard quotient was set to 1.

2.4 Results and Discussion

According to the exposure/hazard model for non-cancer effects, the combined ingestion, inhalation, and dermal uptake may lead to allowable concentrations in carpet fiber ranging from approximately 8 to 132 mg tPCBs/kg depending on the magnitude of the bioavailability and volatilization retention factors (Table 2; Figure 1). In contrast, the acceptable concentrations of tPCBs in carpet fiber associated with a 1 in 1 million cancer risk are much higher and range from approximately 39 to 660 mg/kg (Table 3; Figure 2). Comparing the tPCB concentrations reported in the finished product (carpet), which reached a maximum of 3.8 mg/kg in one carpet brand, to the results from the current assessments suggests that, even at 100% bioavailability and 1% volatilization retention, it is highly unlikely that the population will experience any unacceptable cancer or non-cancer risk/hazard responses. This observation is made despite the excessive amount of conservatism built into the current screening-level risk assessment. Because many of the critical physical/chemical parameters dictating how pigments (and tPCBs) behave in carpet fiber are unknown, this uncertainty was accounted for by intentionally overestimating many of these important factors. Rather than viewing these results as accurate predictors of risk, it is important to understand that, even applying these multiple high-end assumptions, the levels of tPCBs measured in the red pigments represent little or no unacceptable risk.

3. Food Wrap Scenario

The second exposure scenario identified by the CEM as requiring a detailed analysis is the scenario where a polymer film is used as a food contact material. This exposure scenario is based on a dual-layer wrap product, in which the tinted outer non-food contact layer of the wrap contains the affected pigment. The analysis of this scenario focuses on emulating the U.S. Food and Drug Administration (FDA) assessment published in the Federal Register Notice (Notice) (62 Fed. Reg. 9365, March 3, 1997) for a pigment colorant in polymers intended for use in contact with food.

3.1 Federal Register Notice

The FDA evaluated the safety of Pigment Red 254 used as a colorant in polymers intended as packaging material for food (62 Fed. Reg. 9365, March 3, 1997). Pigment Red 254 could contain inadvertently generated PCBs as permitted under applicable regulations. However, the FDA concluded that there is a reasonable certainty that no harm from exposure to tPCBs would result from the proposed use of the pigment in food packaging. The agency stated that it would not expect that the inadvertent impurity (tPCBs) would become a component of food at other than extremely low levels. This conclusion of no risk was based on the upper-bound calculated human cancer risk of less than 7.5×10^{-13}. The actual lifetime-averaged individual exposure (and risk) to tPCBs is likely to be substantially less because very conservative assumptions were used to set the worst-case scenario employed by the FDA.

3.2 Pigment Red 144/214 in Cheese Wrap

We expect that the PCB contaminants in Pigments Red 254 and 144/214 behave in a similar fashion, and it is very plausible that the methodology used by the FDA is applicable for both pigments. We repeated the risk analysis for Pigment Red 144 and 214 to capture the case-specific concentration of 1.1 mg tPCBs/kg in the film used to wrap cheese (BBL, 2004). The cheese food category encompasses cheeses such as blue, brick, camembert, brie, cheddar, gouda, edam, limburger, mozzarella, parmesan, Swiss, cream, and processed. Exposure parameters relevant to that food group were obtained from Smiciklas-Wright et al. (2002).

In the current assessment, a conservative assumption was made that the entire residue of tPCBs contained in the outer layer of the film would transfer through the inner layer to the food item instantly. Thus, assuming that each square inch of film contacts 10 grams of food (the FDA's standard assumption) and that the film face weight is 0.035 g/in^2 (Clariant, undated), the maximum concentration of tPCBs in the contacted food (cheese) is

0.00385 mg/kg cheese[1]. The actual amount and rate of the tPCB transfer are likely much lower because the pigment is contained in the separate outer layer, which is not in immediate contact with food. Also, it would be expected that migration under refrigerated conditions should occur only at a slow rate, if at all. Thus, it is probable that the pigment never becomes incorporated into the food material.

To estimate the tPCB exposure of a person eating cheese, the calculated tPCB concentration must be multiplied by the amount of cheese consumed by a typical consumer. According to Smiciklas-Wright et al. (2002), average consumption of cheese is 0.026 kg per person per day. Given the average body weight of an adult of 70 kg, the exposure rate to tPCBs is 0.0000014[2] mg tPCBs/kg BW/day.

3.3 Results and Discussion

Comparing the calculated exposure to the non-cancer hazard threshold of 0.00002 tPCBs mg/kg BW/day (Table 1) reveals that the worst-case cheese exposure is about 15-fold lower than the trigger associated with non-cancer effects.

To estimate cancer risk, the estimated daily exposure must be averaged over a lifetime. According to Pao et al. (1990), the maximum consumption rate of natural cheese for all age groups and genders is 16.2%. Assuming that there are three meals per day, the number of eating occasions in one year equals to 1,095. Thus, the number of eating occasions where cheese is consumed equals to 177.39. Assuming three meals per day, the annual rate of cheese consumption is equivalent to approximately 59 days. This number was used as the exposure frequency. Exposure duration was set to 70 years, and the averaging time was set to 25,550 days. Multiplying the daily exposure rate of 0.0000014 mg tPCB/kg BW/day by 59 days/year and 70 years and dividing the product by 25,550 days yields a lifetime-averaged exposure rate of 0.0000002 mg tPCB BW/day. In terms of the cancer risks (0.00001429 mg tPCB/kg BW/day; Table 1), the estimated exposure resulting from cheese consumption is about 63 times lower than that needed to exceed the cancer level risk of 1 in 1 million.

This analysis shows that the potential exposure to tPCBs resulting from eating cheese wrapped in red film is very low and highly unlikely to result in any toxicological responses in the population at large.

[1] 1.1 mg tPCBs/kg film x 0.000035 kg film /in^2 film x 1 in^2 /0.01 kg food (cheese) = 0.00385 mg tPCB/kg food (cheese)
[2] 0.00385 mg tPCBs/ kg cheese x 0.026 kg cheese/person/day x person/70 kg = 0.0000014 mg tPCBs/ kg BW/day

4. Uncertainty

Because of the current methodology required to estimate exposure and toxicity, uncertainty is inherent in the risk assessment process. Uncertainty in this context is attributed to either a lack of knowledge (referred to as "incertitude") or natural variability. Incertitude can be addressed by collecting additional information (i.e., obtaining additional exposure-related data), while uncertainty attributable to natural variability cannot easily be reduced.

The performance of the quantitative assessment, and the development of risk-based tPCB concentrations associated with the exposure pathways identified as "complete" in the CEM, have a number of uncertainties. These uncertainties fall primarily in the category of incertitude and are attributable to a lack of knowledge or information. While some of the parameters used to characterize exposure were obtained from USEPA guidance documents or the published literature, many important inputs were based on best professional judgment. Similarly, not only were characterization variables estimated, but some of the more basic information, such as the actual concentration of tPCBs in a home carpet, was estimated or based on internal calculations.

While this estimate was based on limited empirical data, the concentration in the carpet actually contacted by the hypothetical receptor was assumed to be reflective of a carpet containing 100% red pigment (Pigment Red 144 and/or 214). Although no surveys were conducted to bound the uncertainty associated with this assumption, it is unlikely that bright red carpet (i.e., approximating 100% red pigment) is actually used in a *household* setting. To the contrary, industry representatives indicate that red pigment would generally not be used as the sole colorant in household carpets. Making the assumptions that an individual was exposed only to bright red carpet, and that the carpet was composed entirely of fibers with Pigment Red 144/214, significantly overestimates the exposure to tPCBs and, therefore, the risks and hazards associated with this pathway. The magnitude of this overestimation cannot be quantified at this time, but it is undoubtedly substantial, perhaps ranging over several orders of magnitude. Indeed, if fibers containing Pigment Red 144 or 214 comprise only 10% of the carpets that were actually manufactured, the risk-based concentrations presented in Table 2 would increase by an order of magnitude based solely on this one variable.

Additionally, if the carpets that were actually manufactured using Pigment Red 144 and/or 214 were not used in residential settings (as assumed in this screening-level risk assessment), but rather in industrial settings, then the risk-based concentrations in Table 2 would increase as well. Non-residential uses eliminate frequently exposed young children as receptors of concern (the most heavily exposed receptor), thereby eliminating two high-end

pathways of exposure – constant, direct dermal contact with carpet and ingestion of tPCBs as a result of mouthing behavior.

Because of the unique nature of the hypothetical situation evaluated in the assessment, it was necessary to modify the standard default values and adapt them to the conditions assumed in the scenario. While data characterizing the "carpet scenario" are not specified in any USEPA guidance document, certain assumptions were made based on best professional judgment. For example, it was assumed that the primary exposure pathways were ingestion of liberated fibers, dermal contact with the fibers in the carpet, and inhalation of tPCB vapors emanating from the carpet fiber. In reality, due to the specifics of the manufacturing processes, the exposure pathways are likely to be insignificant. In producing colored carpets, the pigment is permanently encapsulated in the polymer shell of the fiber during the coloring process. This encapsulation process effectively reduces the potential for the pigment to mobilize off the fiber material. During the early phase of this project, Clariant determined that tPCBs could be effectively extracted from a polymer matrix only with a non-polar solvent such as hexane, and that using water for such extractions yielded no detectible levels of tPCBs. Therefore, the assumption that a significant amount of the pigment (and associated tPCBs) are released from the fiber and are free to be absorbed in the gastrointestinal tract, enter the skin, or volatilize into the surrounding air to be inhaled, are not based on any empirical data, but rather represent a worst-case exposure scenario. Thus, modifying the relative bioavailability factor to account for the likelihood that only a small fraction, if any, would be absorbed is a reasonable approach. Because there are no data specifically available on the bioavailability, we chose to vary the factor from 100% to 1% to reflect the impact this had on the outcome. Again, based on the process chemistry associated with carpet manufacturing, a reasonable expectation is that the actual bioavailability is on the low end of this range.

Addressing uncertainty by overestimating certain parameters is a standard technique in the USEPA-promulgated process. However, making these assumptions in order to complete the assessment does not suggest that Clariant endorses, or has information to support, these exposure parameters. In fact, observational data suggest that pigments (and associated tPCBs) are not readily transferred directly from the fiber to the skin because individuals routinely in contact with carpet do not show obvious signs (i.e., color) on their skin or clothes. Likewise, significant transfer of pigment off the fiber would result in obvious fading over a relatively short period of time. Again, this is not routinely observed. Therefore, this direct transfer of tPCBs would not occur in quantities that might represent significant exposure (on the skin or ingested via hand-to-mouth activity), nor to the extent assumed in this exposure model. Therefore, this direct transfer of tPCBs would not occur in quantities that might represent significant exposure (on the skin or ingested via hand-to-mouth activity).

Similarly, the volatilization retention factors used in the inhalation exposure model were based on best professional judgment because no empirical data are available. The assumed volatilization retention factors of 0.1% to 1% were based on consideration of the manufacturing and end-use conditions. As previously noted, during the production of colored carpets, the pigment is permanently encapsulated in the polymer shell of the fiber during the coloring process. This process would dramatically reduce any potential for PCB molecules to volatilize off the fiber.

The volatilization factor calculated here, using work by Bennet and Furtaw (2004), examines the dynamics of volatile substances from carpet in a closed system. It implicitly accounts for sorption/desorption dynamics. However, it deals only with surfaces of an applied film, and not carpet fiber matrix, where the pigment is encapsulated. Therefore, the *VRF* is used to model the proportion of tPCBs that may be liberated from the *interior* of the fiber, where the *VF* from Bennet and Furtaw (2004) account from movement from the *surface* of the carpet into air. Also, explicit in the model used to estimate air concentration, the amount of tPCBs in the fiber represents an infinite, inexhaustible source (i.e., the concentration term stays constant). Use of higher, physically unlikely, volatilization retention factors would require that tPCBs be replenished because volatilization rates of 10% or higher over a 10-year period would substantially reduce the source of tPCBs in the fiber. Assuming that these higher volatilization rates would require the development of a first-order decay function for use in the exposure model, this decay factor and higher volatilization rates would result in depleted tPCB concentrations in the fiber and, therefore, much lower air concentrations over time than those assumed in the current assessment.

An additional uncertainty includes the methodology used to model carpet concentrations resulting in "acceptable" air concentrations. The model used (Bennett and Furtaw, 2004) derives equilibrium partition coefficients to various surface components. These values have traditionally been determined "by releasing a low concentration of the compound of interest into a nonreactive chamber and with a sample of the material (e.g., carpet) of interest, followed by a desorption period. The air concentration throughout the experiment is measured, and from this adsorption, desorption and partitional coefficients can be derived." Although somewhat applicable, in this situation, the tPCB containing pigment is permanently encapsulated in the polymer shell of the fiber during the coloring process. As a result, the simple aerial application of materials and the resulting flux, as described by the Bennett and Furtaw model, will result in an overestimation of the volatilization of tPCBs.

There are also experimental data to support the use of these low volatilization rates. Qi (2003) reported that, on average, 5% of pure PCBs placed on glass volatilized into the air. Since this volatilization occurred under favorable conditions, it is considered a high-end estimate. Because the manufacturing process encapsulates the pigment in the polymer shell of the fiber, this upper estimate is not particularly relevant to the carpet exposure scenario, although it does provide support for the selection of the volatilization rates used in the screening-level assessment.

One acknowledged data gap is associated with the above discussion. Because the colorization/encapsulation process is unique, there are no available data that can be directly extrapolated to the exposure scenario. Thus, perhaps the greatest source of uncertainty, in terms of impacting the estimate of an internal dose of tPCBs, is the amount of tPCBs liberated from the fiber that can be absorbed across biological membranes. Because of this uncertainty, the screening-level risk assessment used a range of bioavailability and volatilization retention factors to estimate exposure. Based on manufacturing processes and observational data that illustrate that the pigments are tightly bound to the fibers, assumptions above even 10% are significantly overestimating exposure and, therefore, risk. However, additional data would be required to quantify the magnitude of this overestimation.

Other uncertainties that were addressed by conservative estimates include the assumption that fiber particles behave like soil in terms of estimating dermal exposures. Adherence factors, in particular, are likely overestimating the time and the amount that the fiber is in direct contact with the skin. Similarly, in a house that is kept clean and vacuumed, the contribution of carpet fiber to the house dust would be minimal. Thus, the assumption of an ingestion rate of 55 mg/day is not based on any scenario-specific information, but rather is based on estimates from studies on children playing outdoors. Again, adopting this exposure factor likely overestimated dust ingestion.

5. Conclusions

The purpose of this screening-level risk assessment was to satisfy a request from the USEPA to provide a bounding estimate on the hypothetical risks and hazards that might have been associated with a one-time past use of red pigments produced by Clariant that were subsequently found to contain trace concentrations of tPCBs. These pigments are no longer produced or sold by the Clariant Corporation, and are no longer being inserted into commerce where they could potentially be contacted by the public. However, in order to attempt to place into context the upper bound estimate of theoretical risks associated with these past uses, risk-based concentrations associated with two scenarios with a potential for exposure to sensitive human receptors were developed. Based on a qualitative evaluation of all products and intermediates potentially containing the pigments, the exposure pathways selected for this evaluation were considered, in theory, the most quantitatively significant.

As noted in the Uncertainty section (Section 4), data specific to the exposure pathways analyzed in this report are limited. In attempt to account for this limited information, and to address any potential risks associated with the use of Pigment Red 144 and 214 in consumer products, theoretical exposures were intentionally overestimated. Even under these high-end exposure assumptions, the concentrations determined to be within the USEPA's acceptable risks range and hazard thresholds were well above the maximum concentration of tPCBs detected in the pigmented products. Despite the use of intentional overestimates of exposure, the current analysis indicates that there was no unacceptable risk, and that there are no obvious public health concerns.

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7. Tables

Table 1
Exposure/ Risk Model Input Parameters

Parameter	Value	Source
General		
Exposed Population: Young Children (yrs)	1 to 10	USEPA (2000)
Body Weight (1 to 12 yrs old; kg)	21.8	USEPA (2000)
Carpet Life Span (yrs)	10	Bigger and Bigger (2004)
Exposure Duration (yrs)	10	Equal to Carpet Life
Exposure Frequency (days/year)	350	USEPA (1997; 2002)
Life Expectancy (yrs)	70	USEPA (1997; 2002)
Averaging time: non-cancer (days)	3,650	USEPA (1997; 2002)
Averaging time: cancer (days)	25,550	USEPA (1997; 2002)
Ingestion		
Dust (soil) ingestion rate (children; mg dust/ day)	55	Moya et al. (2004)
Bioavailability of PCBs in Fiber (ingestion and inhalation; %)	1, 5, 10, 50, and 100	Assumption
Inhalation		
Inhalation rate (1 to 10 yrs old; m^3/day)	10.4	USEPA (2000)
Complete air exchange rate (1/week; based on 18 exchanges/day)	126	Murray and Burnmaster (1995)
Vapor pressure of PCB44/70 mixture (Pa)	0.0069	MacKay et al. (1992)
Carpet thickness (m)	0.01286	RPA (2004)
Carpet area mass (face weight; mg/m^2)	1700000	Carpet USA (2004)
Volatilization retention factor (unitless)	0.001 to 0.1	Assumption
Dermal		
Dust adherence factor for children post-activity indoors on hands, arms, legs, feet (mg/cm^2)	0.00724	USEPA (2000)
Contact skin surface area during warm-weather play with 32% skin exposed (cm^2/day)	2,763	USEPA (2000)
Dermal uptake factor	0.14	USEPA (2001)
Hazard and Risk Reference Values		
Target hazard quotient	1	USEPA (1997; 2002)
Non-cancer reference dose (mg/kg BW/day)	0.00002	USEPA (2002)
Cancer slope (mg/kg BW/day)$^{-1}$	0.07	USEPA (2002)
Target cancer risk	1×10^{-6}	USEPA (1997; 2002)
Target lifetime average daily dose (mg/kg BW/day)	0.000014	equal to acceptable risk over cancer slope

Table 2
Summary of Congener Analysis by Alta Labs
Homolog Level
(Percent)

Lot Sample	US62253701	USEA000373	US62254106	1746-97-12	1746-97-13	1746-97-14	1746-97-15	1746-97-04	1746-97-5	1746-97-6	1746-97-1	1746-97-2	1746-97-3	1746-97-7	1746-97-8	1746-97-9	1746-97-10	1746-97-11
PCB Homolog (Congener Range)	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
mono (1-3)	0.0016	0.0055	0.00089	0	0	0	0.00067	0.00090	0	0	0	0	0	0	0	0	0	0.0043
di (4-15)	0.010	0.013	0.011	0.0058	0.0048	0.0044	0.0064	0.0050	0.0053	0.0044	0	0.0025	0.0017	0.0021	0.0019	0.019	0.0050	0.0079
tri (16-39)	0.53	0.65	0.55	0.34	0.31	0.36	0.37	0.36	0.37	0.26	0.38	0.37	0.39	0.37	0.38	0.30	0.24	0.25
tetra (40-81)	99.091	98.94	99.059	99.41	99.49	99.38	99.44	99.52	99.44	99.52	99.39	99.38	99.38	99.48	99.47	99.46	99.53	99.52
penta (82-127)	0.34	0.37	0.36	0.23	0.18	0.25	0.18	0.093	0.17	0.20	0.22	0.24	0.21	0.14	0.15	0.21	0.22	0.21
hexa (128-169)	0.023	0.024	0.018	0.0093	0.0090	0.013	0.0072	0.012	0.0093	0.0091	0.014	0.011	0.016	0.0090	0.0090	0.014	0.0082	0.0091
hepta (170-193)	0.00020	0	0	0	0	0	0	0.00016	0	0	0	0	0	0	0	0	0	0
octa (194-205)	0	0.000079	0	0	0	0	0	0.000091	0	0	0	0	0	0	0	0	0	0
nona (206-208)	0.00013	0	0	0	0	0	0	0.000011	0	0	0	0	0	0	0	0	0	0
deca (209)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Total Mono-Tetra	99.63	99.61	99.62	99.76	99.81	99.74	99.82	99.89	99.82	99.79	99.77	99.75	99.77	99.85	99.85	99.77	99.77	99.79
Total Penta-Deca	0.37	0.39	0.38	0.24	0.19	0.26	0.18	0.11	0.18	0.21	0.23	0.25	0.23	0.15	0.15	0.23	0.23	0.21

Table 3
Risk-Based Concentrations (mg/kg) of tPCBs in Carpet Fiber

Oral Bioavailability Factor	Acceptable Concentration in Carpet Fiber (mg tPCB/kg)		
	Volatilization Retention Factor		
	0.001	0.005	0.01
Non-Cancer Hazard			
0.01	133	122	111
0.05	81	77	72
0.10	54	52	50
0.50	15	15	15
1.00	7.9	7.8	7.8
Cancer Risk			
0.01	664	610	554
0.05	404	384	361
0.10	271	262	251
0.50	75	74	73
1.00	39	39	39

8. Figures

Figure 1. Risk-Based Concentrations of tPCBs in Carpet Fiber for the Non-Cancer Exposure Scenario Given Bioavailability and Volatilization Retention Factors (VRF)

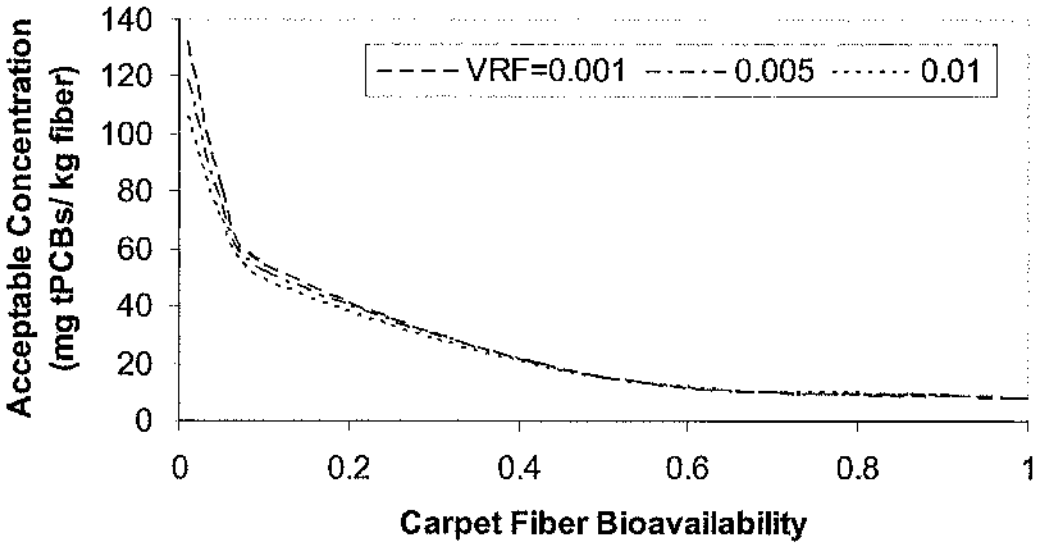
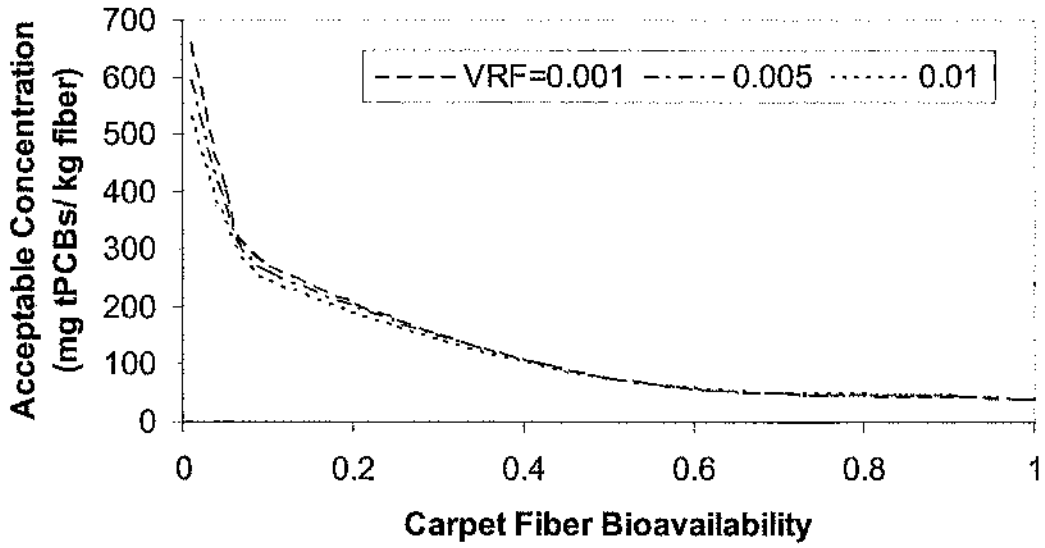


Figure 2. Risk-Based Concentrations of tPCBs in Carpet Fiber for the Cancer Exposure Scenario at Given Bioavailability and Volatilization Retention Factors (VRF)



BBL	Blasland, Bouck & Lee, Inc.
CEM	Conceptual Exposure Model
FDA	U.S. Food and Drug Administration
PCB	polychlorinated biphenyl
ppm	parts per million
tPCBs	total polychlorinated biphenyls
PCDD	polychlorinated dibenzodioxin
PCDF	polychlorinated dibenzofuran
RPA	Radiant Panel Association
USEPA	U.S. Environmental Protection Agency
VF	Volatilization Factor
VRF	Volatilization Retention Factors

Clariant Corporation

4000 Monroe Road
Charlotte, NC 28205
704.331.7000

Via FedEx

February 21, 2005

Kimberly Tisa, PCB Coordinator (CPT)
U.S. Environmental Protection Agency
1 Congress Street, Suite 1100
Boston, MA 02114-2023

RE: Draft Exposure and Screening-Level Risk Assessment, Red Pigment Project

Dear Ms. Tisa:

Clariant is responding to the January 25th EPA and Versar comments on the document titled *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, December 6, 2004*. The comments are directly and sequentially addressed in the enclosed letter from Clariant's consultant, BBL Sciences. Also enclosed are two copies of the revised risk assessment report which now reflect our responses to the comments.

As stated in the cover letter to the December 6, 2004 report, Clariant had just received congener-specific analyses of several commercial pigment lots from Alta Laboratories, El Dorado Hills, CA. The results of these analyses prompted additional in-house re-testing of certain pigment lots over the past several weeks in order to verify their total PCB concentration. For some lots, significant disparities exist between the results from the two analytical labs.

We are attempting to resolve these disparities by close examination and review of the methods used by each lab. The in-house re-testing program should be completed this week. Additional testing of the few remaining pigment lots not yet analyzed by Alta Laboratories is expected to be completed by them on March 2. Once all results are available, a final determination will be made regarding the most appropriate total PCB

concentration to use in the carpet scenario risk assessment. If necessary, a revised risk assessment report will be submitted no later than March 31, 2005.

In the meantime, we look forward to your response to today's submittal. If you have any questions or need additional information, please feel free to contact me at 704-331-7104 or via email at mike.teague@clariant.com

Sincerely,

CLARIANT CORPORATION

Michael A. Teague, Ph.D.
Vice President / ESHA

Enclosures

cc: Erin Russell, Esq.
John Schell, Ph.D.
John Paul
Robert Freet, Ph.D.

Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205
704.331.7000

Via FedEx

February 7, 2005

Kimberly Tisa, PCB Coordinator (CPT)
U.S. Environmental Protection Agency
1 Congress Street, Suite 1100
Boston, MA 02114-2023

RE: Schedule for Response to Comments on Exposure and Screening-Level Risk Assessment, Red Pigment Project

Dear Ms. Tisa:

Clariant is responding to your letter dated January 25, 2005 in which EPA provided comments to the *December 6, 2004 Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214*. In this letter, you requested that Clariant provide the Agency with an estimated schedule for completion of the revised assessments.

Clariant continues to work with its consultant, BBL Sciences, to address the most recent comments. Our responses will be completed and submitted to you no later than February 21, 2005.

If you have any questions or need additional information, please feel free to contact me at 704-331-7104 or at mike.teague@clariant.com

Sincerely,

CLARIANT CORPORATION

Michael A. Teague, Ph.D.
Vice President / ESHA

cc: Erin Russell, Esq.
John Schell, Ph.D.
John Paul
Robert Freet, Ph.D.